IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
BIONPHARMA INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Bionpharma Inc. ("Bionpharma"), Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate"), by and through its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 10,772,868 (the "'868 Patent") arising under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Bionpharma of Abbreviated New Drug Application ("ANDA") No. 212408 with U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® Product." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Bionpharma's infringement of the '868 Patent.

THE PARTIES

2. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 8 Cabot Road, Suite 2000, Woburn MA 01801.

3. Silvergate is a wholly-owned subsidiary of Azurity Pharmaceuticals, Inc. ("Azurity").

4. On information and belief, Bionpharma is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 600 Alexander Rd., #2-4B, Princeton, NJ 08540. On information and belief, Bionpharma is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the U.S. market.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

6. This Court has personal jurisdiction over Bionpharma because, among other things, on information and belief, Bionpharma is a corporation formed under the laws of the State of Delaware.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

SILVERGATE'S EPANED® PRODUCT

8. Silvergate's Epaned® Product is an FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

9. Azurity is the holder of approved NDA No. 208686.

PATENTS-IN-SUIT

10. The '868 Patent, entitled "Enalapril Formulations," issued on September 15, 2020 from United States Patent Application 16/242,898 (the "'898 Application"). A true and correct copy of the '868 Patent is attached to this Complaint as Exhibit A.

11. The ’868 Patent was duly and legally issued to Silvergate as the assignee. Silvergate owns all rights, title and interest in the ’868 Patent.

12. Pursuant to 21 U.S.C. § 355, Azurity submitted a request to FDA to list the ’868 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 208686 (Silvergate’s Epaned® product).

13. Silvergate’s Epaned® product is covered by at least one claim of the ’868 Patent.

INFRINGEMENT BY BIONPHARMA

14. By letter dated October 30, 2018 (“the First Notice Letter”), Bionpharma notified Silvergate that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. §314.95) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate’s Epaned® product (“the Bionpharma ANDA Product”) before the expiration of three Silvergate Patents related to Epaned®: United States Patent Nos. 9,669,008 (the “’008 Patent”), 9,808,442 (the “’442 Patent”), and 10,039,745 (the “’745 Patent”)[1].

15. By an additional letter dated April 25, 2019 (“the Second Notice Letter”), Bionpharma notified Silvergate that it had submitted ANDA No. 212408 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. §314.95) seeking approval to engage in the commercial manufacture, use, and sale

[1] On December 12, 2018, Silvergate brought an action against Bionpharma for infringement of the ’008 Patent, the ’442 Patent, and the ’745 Patent in this District. That case is currently pending as C.A. No. 18-1962-LPS. Silvergate hereby incorporates by reference its Complaint (D.I. 1) against Bionpharma in that action, and intends to request consolidation of these related cases.

of the Bionpharma ANDA Product before the expiration of another Silvergate patent: United States Patent 10,154,987 (the "'987 Patent").[2]

16. Each of the '008, '442, '745, '987, and '868 patents expire on March 25, 2036.

17. Upon information and belief, Bionpharma intends to engage in commercial manufacture, use, and sale of the Bionpharma ANDA Product promptly upon receiving FDA approval to do so.

18. Upon information and belief, Bionpharma is seeking approval to engage in the commercial manufacture, use, and sale of the Bionpharma ANDA Product before the expiration of the '868 patent.

19. By filing ANDA No. 212408, Bionpharma has necessarily represented to FDA that the Bionpharma ANDA Product has the same active ingredients as Silvergate's Epaned® product, has the same route of administration, dosage form, and strength as Silvergate's Epaned® product, and is bioequivalent to Silvergate's Epaned® product.

CLAIM 1 FOR RELIEF

Infringement of the '868 Patent Under 35 U.S.C. § 271 (e)(2)(A)

20. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

21. Bionpharma submitted ANDA No. 212408 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Bionpharma ANDA Product throughout the United States. By submitting the ANDA, Bionpharma has committed an act of infringement of the '868 Patent under 35 U.S.C. § 271 (e)(2)(A).

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[2] On June 7, 2019, Silvergate brought an action against Bionpharma for infringement of the '987 Patent in this District. That case was consolidated with C.A. No. 18-1962-LPS.

22. If Bionpharma's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Bionpharma ANDA Product will constitute acts of infringement of the '868 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

23. On information and belief, Bionpharma has actual and constructive knowledge of the '868 Patent and the '898 Application. In addition, upon information and belief, Bionpharma has specific intent to infringe the '868 Patent. Moreover, there are no substantial non-infringing uses for the Bionpharma ANDA Product other than as the pharmaceutical claimed in the '868 Patent.

24. The commercial manufacture, use, offer for sale, sale, and/or importation of the Bionpharma ANDA Product in violation of Silvergate's patent rights will cause irreparable harm to Silvergate for which damages are inadequate.

PRAYER FOR RELIEF

Silvergate respectfully requests the following relief:

a) A judgment that Bionpharma has infringed the '868 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212408 under Section 505(j) of the FDCA, and that Bionpharma's making, using, offering to sell, or selling in the United States, or importing into the United States of the Bionpharma ANDA Product will infringe one or more claims of the '868 Patent;

b) A finding that the '868 Patent is valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212408 shall be a date which is not earlier than the latest expiration date of the '868 Patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Bionpharma, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or importation into the United States, of any drug product covered by the '868 Patent, including the Bionpharma ANDA Product;

e) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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